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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,814	06/07/2007	Salah-Dine Chibout	4-33318A	3904

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	
MAIL DATE	**DELIVERY MODE**
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,814	CHIBOUT ET AL.	
	Examiner	Art Unit	
	JACOB CHEU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12,26-28,30 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12,26-28,30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/18/07; 6/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant elected species CD59 for prosecution on 10/24/08 with traverse is acknowledged.

Applicant argues that although the instant method can be practiced by only one of the peptides from Table 11, however the instant method are more corroborative if more than one of the peptides selected from Table 11 are employed. Furthermore, Applicant argues that it would not impose serious burden for search purpose if more biomarkers are employed.

2. Applicant's arguments have been considered, but are not persuasive. The claim language clearly requires only *ONE* species for detection of coronary disease (See claim 10)(emphasis added). For the purpose of prosecution, election of ONE species for current examination is deemed proper. Moreover, each biomarker in Table 11 is different in terms of physical, chemical and physiological characteristics. This requires search in different fields and would impose serious burdens. In addition, Examiner hereby selects one more species, i.e. fibrinogen gamma chain, for prosecution purpose. Currently, TWO species are under examination, namely CD59 and fibrinogen gamma chain.

3. Claims 10-12, 26-28, 30 and 34 are under examination. Claims 1-9, 13-25, 29, 31-33 and 35-88 are cancelled. Note, claim 27 is interpreted as the same as claim 26 having plurality of peptides selected from Table 11.

Priority

The provisional application 60574818 supports CD59 biomarker for diagnosis of coronary artery disease. Therefore, the priority of instant invention is accorded 5/27/2004.

Claim Objections

4. Claims 10-12 are objected to because of the following informalities:

With respect to claim 10, the steps are not complete since after step (c), it is needed to indicate the difference is indicative of coronary artery disease in a subject.

With respect to claim 11, line 3, "Predominant" should be "predominant".

With respect to claim 12, same as claim 11 for "predominant".

With respect to claim 11 and 12, the symbol ">" should be recited "greater than".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-12 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With Respect to claim 11, it is not clear what Applicant means "predominant". If this "predominant" means increased level compared to the control, there is no need for such feature been recited. In addition, there is no need for "disease > control" if the level of the peptide of Table 11 is increased in the subject compared with that of the control, it would be indicative of the coronary artery disease. Similarly claim 12 suffers the same problem.

With respect to claim 30, line 1, "said protein" lacks antecedent basis.

With respect to claim 12, it would be mutually exclusive if the CD59 is predominant in disease state (See below). Note, CD59 is the "ONE" peptide selected from Table 11. Hence, if claim 12 dependent from claim 10, this would be *in conflict with* claim 11 (emphasis added).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10, 11, 28, 30 and 34 rejected under 35 U.S.C. 102(b) as being anticipated by Vakeva et al. (Scan J. Immunology 2000 Vol. 52, page 411-414).

Vakeva et al. teach a method of identifying coronary artery disease, e.g. acute myocardial infarction (AMI). Vakeva et al. teach measuring the plasma level of CD59 from the AMI patients. The results show that the level of CD59 increases in AMI patients compared with health control (See Abstract). The assay was conducted using antibody against CD59 (See page 412, Methods).

9. Claims 10, 11, 30 and 34 rejected under 35 U.S.C. 102(b) as being anticipated by Seifert et al. (Atherosclerosis 1992 Vol. 96, page 135-145).

Seifert et al. teach a method of detecting atherosclerosis from the patients. Seifert et al. teach measuring CD59 levels in the samples of atherosclerosis patients. Seifert et al. report an increased level of CD59 is found in the atherosclerosis lesion cells (See Abstract). The detection is also used anti-CD59 antibody (See page 136, right column, Materials and Methods).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifter et al. in view of Jones (US 20020015950).

Seifter et al. reference has been discussed and Seifter et al. teach the increased level of CD59 is indicative of atherosclerosis. However, Seifter et al. do not teach combining another peptide, such as fibrinogen gamma chain peptide for diagnosis of coronary artery disease.

Jones et al. teach fibrinogen gamma chain is associated with coronary artery disease, such as atherosclerosis (See Section 0010; Abstract polypeptide).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention was made to have motivated Seifter et al. to combine another biomarker, such as fibrinogen gamma chain as taught by Jones, to diagnose atherosclerosis in patients. One ordinary skill in the art would have been motivated to

combine more biomarker in order to have a more sensitive and more accurate evaluation of atherosclerosis.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641